510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K031359

B. Analyte:
Blood collection tube

C. Type of Test:
Collection, processing and transportation of a plasma sample for Nucleic Acid Testing (NAT)

D. Applicant:
Sarstedt Inc.

E. Proprietary and Established Names:
S-Monovette® EDTA K_2-Gel

F. Regulatory Information:

1. Regulation section:
   862.1675; Tubes, vials, systems, serum separators, blood collection
2. Classification:
   Class II
3. Product Code:
   JKA
4. Panel:
   75

G. Intended Use:

1. Indication(s) for use:
   The S-Monovette® EDTA K_2-Gel tube provides a means for collection, processing, and transportation of a plasma specimen in a closed system. Following collection of the blood, the S-Monovette® EDTA K_2 Gel is to be centrifuged such that the gel creates a barrier between the plasma and cellular components. The plasma specimen can then be removed for testing or the specimen can then be removed for testing, or the specimen can be transported for testing at another location without the plasma mixing with the cellular components. The plasma specimen produced by the S-Monovette® EDTA K_2 Gel can be used for Nucleic Acid Testing (NAT) by methods such as PCR - Polymerase chain reaction or other procedures where the laboratory has determined that a plasma specimen is appropriate.
2. Special condition for use statement(s):
   NA
3. Special instrument Requirements:
   NA

H. Device Description:
The S-Monovette® EDTA K_2 Gel tube is manufactured from plastic materials and incorporates a screw cap with membrane, a tube, a plunger, and a piston. The screw cap is designed with three pins which function as a lock for the needle to attach. The

S-Monovette® can be filled by two methods: the vacuum principle and the aspiration principle. In the vacuum principle, the S-Monovette® is evacuated prior to blood collection by pulling the plunger until the piston locks in the base of the tube. Once this occurs, the plunger is broken off. The needle is inserted into the vein, the pre-evacuated S-Monovette® is then attached to the needle by inserting the cap onto the back of the needle and turning the S-Monovette® clockwise to lock the pins. Multiple samples can be taken without removing the needle from the vein by removing the previous S-Monovette® by turning it counter-clockwise to unlock the pins and then inserting the next S-Monovette®. In the aspiration principle, the S-Monovette® is attached to the needle and the needle is inserted into the vein. The blood is drawn into the S-Monovette® by the user pulling back on the plunger until the piston reaches the base of the tube. The S-Monovette® is removed from the needle and the piston is locked in the base of the tube. Multiple samples can be taken in the same manner. This principle allows the user to adjust the flow rate into the S-Monovette®. EDTA K_2 is used as the anticoagulant and an acrylic/silicon gel for separation. The S-Monovette® EDTA K_2 Gel is available in 4.9 and 9.0 mL volumes.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Sarstedt S-Monovette® EDTA tube
2. Predicate K number(s):
   Pre-amendment
3. Comparison with predicate:

Similarities		
Item	S-Monovette® EDTA K_2	S-Monovette® EDTA
Material	Plastic	Plastic
Collection method	Aspiration principle or vacuum	Aspiration principle or vacuum
Differences		
Item	S-Monovette® EDTA K_2	S-Monovette® EDTA
Anticoagulant	EDTA K_2	EDTA K_3
Gel	Acrylic polymer and silicone dioxide mixture	None
Performance	Provides plasma specimen for molecular diagnostic testing (PCR)	No claim

J. Standard/Guidance Document Referenced (if applicable):

ANSI/AAMI/ISO 11137 - 1994, Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization; ISO 6710 - Single Use Containers for Blood Specimen Collection

K. Test Principle:

The mean concentration of 1.6 mg EDTA/mL blood (when filled to the nominal volume specified) serves as an anticoagulant. When centrifuged, the blood sample results in a nearly undiluted plasma sample.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    NA
    b. *Linearity/assay reportable range:*
    NA
    c. *Traceability (controls, calibrators, or method):*
    NA
    d. *Detection limit:*
    NA
    e. *Analytical specificity:*
    NA
    f. *Assay cut-off:*
    NA
2. Comparison studies:
    a. *Method comparison with predicate device:*
    The device was tested by the German Red Cross (DRK) for effect on HBV, HCV and HIV viral load determinations. The performance of this device was compared to its predicate device S-Monovette® EDTA. The whole blood of a donor confirmed to be HBsAg, anti-HCV and anti-HIV negative were spiked with 1000 gE/mL of HCV and HIV RNA, as well as 500 gE/mL of HBV DNA. These specimens were subjected to analysis using 20 S-Monovette® EDTA tubes and 20 S-Monovette® EDTA K_2-Gel tubes, in which virus spiked whole blood was collected. After centrifugation, samples were tested: 1) immediately; (2) after 24hrs storage at room temperature; (3) after 48 hrs and (4) 96hrs storage at 4 ^{0}C. Results from this study: HCV title decreased about 20% after storing the whole blood sample for a period of 24hrs at room temperature and 48hrs or 96hrs at 4 ^{0}C; HIV title decreased about 20% after storing for 96hrs.
    b. *Matrix comparison:*
    NA
3. Clinical studies:
    a. *Clinical sensitivity:*
    NA
    b. *Clinical specificity:*
    NA
    c. *Other clinical supportive data (when a and b are not applicable):*
    NA
4. Clinical cut-off:
    NA
5. Expected values/Reference range:
    NA

M. Conclusion:

Based upon review of the information provided in this 510(k), I recommend that this device is substantially equivalent to devices regulated by regulation 21 CFR 862.1675 Blood specimen collection device; 75 JKA; Class II.